Remarks

Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

I. Claims

Claims 1-11 and 21-24 were pending in this application and these claims stood rejected.

Claims 1, 6 and 24 have been amended to more clearly define the invention. No new matter is added by this amendment.

II. Drawings

On page 2 of the Office Action, the Examiner noted that "[n]ew corrected drawings are required in this application because of the reasons set forth in the attached Draftsperson's review, form PTO-948." Accordingly, Applicant encloses herewith new corrected drawings, Figures 2A, 2B, 2C, 2D1, 2D2, 2D3 and 2E. Applicant believes that the drawings submitted herewith fully comply with 37 CFR §1.84. No new matter is added.

II. Specification

Applicant respectfully submits that the specification has been amended to provide a Brief Description of Figures 5A-5C as required by the Examiner on page 3 of the Office Action. No new matter is added by this amendment to the specification.

The Office Action, on page 3, notes that the specification is not in sequence compliance for the reasons indicated in the STIC Error Report of January 27, 2003. Accordingly, the specification has also been amended to include the sequence listing submitted herewith under § 1.825. A paper copy of the Substitute Sequence Listing consisting of SEQ ID NOS:1-70 is submitted concurrently herewith. Also submitted herewith is a substitute copy of the computer readable form (§ 1.825(b)) of the Substitute Sequence Listing.

Applicant hereby states that the amendments, made in accordance with 37 CFR §1.825(a), included in the substitute sheet(s) of the Sequence Listing are fully supported by the application as filed. No new matter is added. Applicant also states that the enclosed substitute

copy of the computer readable form (substitute CRF diskette) and substitute paper copy of the "Sequence Listing" submitted herewith are identical as required under 37 CFR §1.825(b).

III. Claim Objections

Claim 6 was objected to because of certain informalities as stated on page 3 of the Office Action. Specifically the Examiner noted that the abbreviation, MIE, is not spelled out. Applicant has amended claim 6 to correct the informalities noted by the Examiner. Therefore, Applicant respectfully submits that this objection must be withdrawn.

IV. Rejection of Previously Allowed Claims

Applicant wishes to bring to the attention of the Examiner that some of the pending claims in the Application were previously noted as allowable in the Paper No. 18 (Office Action of January 15, 2002). Now, this Office Action rejects the very same claims that were previously indicated as allowable. Applicant respectfully believes that this rejection runs afoul of the established patent examining procedure for various reasons.

First, pursuant to MPEP § 706.04, a claim noted as allowable shall thereafter be rejected only after the proposed rejection has been submitted to the primary examiner for consideration of all the facts and approval of the proposed action. The examiner should point out in his office action that the claim now being rejected was previously allowed and the Office Action should bear the signature of a Primary Examiner.

Further, when an examiner is assigned to act on an application which has received one or more actions by some other examiner, full faith and credit should be given to the search and action of the previous examiner unless there is a clear error in the knowledge of other prior art. Applicant respectfully submits that the previous Examiner in the Paper No. 18 noted that claims 1-11 and 21-25 are free of prior art and the present Examiner did not establish any error (as will be more readily apparent from the discussion below) in the previous Examiner's knowledge of the prior art. See also MPEP §§ 704.01 and 707.07(g).

V. Rejections Under 35 U.S.C. § 112 First Paragraph, Written Description

The Examiner rejected claims 7 and 8 under 35 U.S.C. § 112, first paragraph as

containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant respectfully traverses this rejection.

The Examiner notes on pages 4-5 of the Office Action that "... The specification only provides a description concerning the binding of Gfi-1 to the consensus sequence prior to its mutation, and does not describe a representative number of sequences that are 65% or 79% homologous to the consensus sequence ... Neither the specification of the instant application or the prior art describes a representative number of Gfi-1 binding sites with 65% or 79% homology to the consensus site that are capable of binding to Gfi-1 prior to, but not subsequent to, mutation. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Applicant respectfully disagrees with these assertions and submits that the specification does recite a sufficient number of representative species, falling within the scope of the genus, including a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. For example, the specification at page 19, line 17 through page 20, line 15, and at page 24, line 12 through page 25, line 6, describe a number of Gfi-1 binding sequences with 65% or 79% homology to the consensus site that are capable of binding to Gfi-1 prior to mutation. Random oligonucleotide selection is described at page 14, line 29 through page 15, line 15. Thus, there is actual reduction to practice of a number of Gfi-1 binding sequences with 65% or 79% homology to the consensus site that are capable of binding to Gfi-1 prior to mutation. Further, for example, Figure 1 shows deduced Gfi-1 binding site. The frequency of the specific base(s) at each position relative to the AATC motif is shown. All or 100% of the selected oligonucleotides contain one AATC motif as do the promoters with potential Gfi-1 binding sites listed in Table 2 (or figures 5A-C after the entry of the present amendment). Thus, there is also a recitation of structural features common to the members of the genus. Given this description in the specification taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the Applicant was

in possession of the invention recited in claims 7 and 8. *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Rejections Under 35 U.S.C. § 112 Second Paragraph

Claims 1-6, 10, 11, 23 and 24 stood rejected under 35 U.S.C. § 112, second paragraph, as indefinite, for the reasons set forth on page 6 of the Office Action. Applicant respectfully traverses this rejection.

The Examiner avers that it is unclear if the claim is referring to the consensus binding site, or if it is referring to another binding site. In response, Applicant respectfully submits that there is nothing unclear about the claim language "binding site for a growth factor independence-1 (Gfi-1) transcription repressor" as one skilled in the art would understand what is meant by this claim term when it is read in light of the specification. For example, the specification at page 11, line 9 through page 12, line 37 teaches that "Gfi-1 is a nuclear protein which binds DNA in a sequence specific manner, and functions as a transcriptional repressor ... This promoter contains two [Gfi-1 binding] sites with 79% and 80% homology to the two Gfi-1 binding site consensus." Thus, this teaching is not clear as to whether the claim is referring to the consensus binding site or to another binding site and those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464 (Fed. Cir. 1993).

The Examiner also avers that the metes and bounds of Gfi-1 binding site are unclear because DNA foot-printing gives a 21 bp overlap with a proposed 12 bp binding site, while DMS interference indicates a 9 bp binding sequence. Applicant disagrees with the Examiner's assertion that DMS interference indicates a 9 bp binding sequence. The specification teaches that DMS methylation interference assays were performed to define the bases in the Gfi-1 binding site that are in contact with the protein and the methylation of guanines at positions 6 and 8 greatly impaired protein DNA binding. See, the specification at page 20, line 32 through page 21, line 6. This teaching in no way contradicts the Applicant's description that "21 bp footprint which extends over the 12 bp binding site." Therefore, the claim language, "binding site for a growth factor independence-1 (Gfi-1) transcription repressor," when read in light of the

specification reasonably apprise those skilled in the art of the scope of the invention. The §112 demands no more. Accordingly, reconsideration and withdrawal of this part of the rejection are respectfully requested.

The Examiner rejected claim 24 on the ground that there is insufficient antecedent basis for the limitation "AATC".

Applicant has made a clarifying amendment to claim 24. Applicant believes that this clarifying amendment obviates the asserted ground for the rejection. Reconsideration is respectfully requested.

VII. Rejections Under 35 U.S.C. § 102

Claims 1-11 and 21-24 stood rejected under 35 U.S.C. § 102 (a) as anticipated by Zweidler-McKay et al., Molecular and Cellular Biology, 1996 (August) 16:4024-4034 Applicant respectfully traverses this rejection.

Zweidler-McKay et al., cannot anticipate the rejected claims under 35 U.S.C. § 102 for, among other things, it was published in August 1996, which was after the Applicant's priority date of June 17, 1996. Accordingly, reconsideration and withdrawal of the rejection based on Zweidler-McKay et al., are respectfully requested.

Claims 1-4 and 7-11 stood rejected under 35 U.S.C. § 102 (b) as being anticipated by Bang et al., U.S. Patent No. 4,992,373, issued February 12, 1991. Applicant respectfully traverses this rejection.

Claim 1 is directed to "[a]n isolated DNA construct comprising at least one binding site for a Gfi-1 transcription repressor, the binding site having a mutation which hinders or prevents binding of said Gfi-1 repressor to the site."

Bang teaches a method for producing recombinant activated protein C directly upon secretion from a eukaryotic host cell and it does not concern Gfi-1 transcription repressor binding sites at all.

"A claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Bristol-Myers Squibb v. Ben Venue*, 246 F.3d 1368, 1374 (Fed. Cir. 2001). Identity of invention requires that a prior reference disclose to one of ordinary skill in the art all elements and limitations of the patent claim. *Scripps Clinic v. Genentech*, 927 F.2d

1565, 1576 (Fed. Cir. 1991). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible, Inc.*, 230 USPQ 81 (Fed. Cir. 1986). "Even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling." *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985).

The claim requires, among other things, the presence of a binding site having a mutation so that binding of the repressor to the site is hindered or prevented. Bang does not anticipate the claimed invention as it does not teach or disclose a Gfi-1 transcription repressor binding site having a mutation which hinders or prevents binding of the Gfi-1 repressor to the site. The claim requires, among other things, the presence of a binding site having a mutation so that binding of the repressor to the site is hindered or prevented. There is no mention of Gfi-1 transcription repressor or Gfi-1 transcription repressor binding site, much less a binding site having a mutation so that binding of the repressor to the site is hindered or prevented. Because the reference does not disclose to one of ordinary skill in the art all elements and limitations of the claimed invention, it fails as an anticipatory reference.

The Examiner avers that a complete deletion of a Gfi-1 binding sequence is within the scope of the claims. Such an interpretation is unnecessary and is unwarranted. The claim requires, as pointed out above, the presence of a binding site having a mutation so that binding of the repressor to the site is hindered or prevented. The specification repeatedly refers to point mutations in the binding site. See, for example, page 11, lines 18-20 and page 20, line 36 through page 21, line 7. These teachings are not directed at the deletion of the entire binding site and Bang does not teach a Gfi-1 transcription repressor binding site, much less a mutated binding site. Therefore, the Bang reference does not anticipate claim 1, or claims depending therefrom.

Claims 1-4 and 7-11 stood rejected under 35 U.S.C. § 102 (e) as being anticipated by Eglitis et al., U.S. Patent No. 5,672,510, issued September 30, 1997. Applicant respectfully traverses this rejection.

Eglitis teaches different retroviral vectors and it does not concern Gfi-1 transcription repressor binding sites at all. Eglitis fails to satisfy the law of anticipation pointed out above. Specifically, Eglitis does not anticipate the claimed invention as it does not teach or disclose a Gfi-1 transcription repressor binding site having a mutation which hinders or prevents binding of the Gfi-1 repressor to the site. The claim requires, among other things, the presence of a binding

site having a mutation so that binding of the repressor to the site is hindered or prevented. There is no mention, in Eglitis, of Gfi-1 transcription repressor or Gfi-1 transcription repressor binding site, much less a binding site having a mutation so that binding of the repressor to the site is hindered or prevented. Because the reference does not disclose to one of ordinary skill in the art all elements and limitations of the claimed invention, it fails as an anticipatory reference.

The Examiner avers that a complete deletion of a Gfi-1 binding sequence is within the scope of the claims. Such an interpretation is unwarranted. The claim requires, as pointed out above, the presence of a binding site having a mutation so that binding of the repressor to the site is hindered or prevented. The specification repeatedly refers to point mutations in the binding site. See, for example, page 11, lines 18-20 and page 20, line 36 through page 21, line 7. These teachings are not directed at the deletion of the entire binding site and Eglitis does not teach a Gfi-1 transcription repressor binding site, much less a mutated site. Therefore, the Eglitis reference does not anticipate claim 1, or claims depending therefrom

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102 are respectfully requested.

VIII. Conclusion

Applicant believes this response to be a full and complete response to the Office Action. Accordingly, favorable reconsideration in view of this response and allowance of all of the pending claims are earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the present application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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